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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,473	07/20/2001	Michael F. McGrath	11916.0049.NPUS00	1751

7590 07/02/2003

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EXAMINER	
MAYES, LAURIE A	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/910,473	Applicant(s) MCGRATH ET AL.	
	Examin r Laurie Mayes	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Objections

Claims 2-6 are objected to as the language "method of 1", "method of 2", etc. should read "method of claim 1", "method of claim 2", etc. Also, claim 5 is objected to as the language "administered on as" is vague and indefinite. The language "administered in approximately" is suggested instead. Appropriate correction is required.

In claim 14, line 2, the term "mammals" should be "mammal's".

In claim 17, line 7, the term "glucocorticoid" is misspelled.

Specification

The use of the trademark POSILAC (p. 16, line 22) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Information Disclosure Statement

The listing of references in the specification on pages 18-20 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Why state that somatotropin is biologically active in a cow? Is there somatotropin that is administered to a cow that is not biologically active? See "a biologically active somatotropin" instead. The claim is indefinite since administering the compound does not necessarily reflect that milk production is induced. A step of induction is absent in the process.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by McFadden et al. (J. Dairy Science 78 (Suppl. 1): 203 (1995) ; cited in IDS, paper #4). McFadden et al. teach a method of inducing milk production in a non-pregnant cows (line 2) (present claim 16), the method comprising administering to cows a milk-secretion stimulation amount of estradiol and progesterone (line 5) administered via a vaginal sponge inserted for more than 6 days (lines 5-7), and BST (bovine somatotropin) (line 3) (present claim 1) that is administered for 15 weeks (line 4) (present claims 2, 4 and 19) in a sustained release dose (lines 3-4) (present

claims 6, 20) in at least four doses every bi-week (line 4) (present claim 5) and wherein the method also comprises administering a milk-secretion enhancing amount of a glucocorticoid approximately 6 days after the estradiol administration (line 6) (present claims 7 and 8). Thus, McFadden teaches all of the elements of claims 1, 2 and 4-8 and these claims are anticipated under 35 U.S.C. 102(b).

Claims 1-3, 19 and 20 and claim 21 dependent thereon are rejected under 35 U.S.C. 102(b) as being anticipated by Kensinger et al. (J. Dairy Science, V. 81, N. S1, p. 210 (1998); previously cited in the PCT International Search Report and in IDS, paper #4). Kensinger et al. teach a method of inducing milk production in cows comprising administering BST for 70 days (lines 11-12) (present claim 19, 20) and .75 mg/kg/day of estradiol-17B (line 8) and .25 mg/kg/day of progesterone for seven days (line 9) (present claims 1-3, 20). Thus Kensinger et al. teach all of the elements of claims 1-3, 19 and 20 and these claims are anticipated under 35 U.S.C. 102(b). Claim 21 is rejected as dependent on a rejected base claim.

Claims 1, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumar et al. (Kumar et al. Indian Journal of Dairy Science, V. 49, N. 10, pp. 664-672 (1996); previously cited in the PCT International Search Report). Kumar et al. teach a method of increasing milk production by administering to buffaloes estradiol-17B and progesterone (p. 665, col. 1, line 11) and BST (line 26) wherein udder massages were given at least twice daily and were also milked twice daily starting on day seven for at least seven consecutive days (p. 665, col. 1, lines 30-38 and col. 2, lines 1-5) (present claims 14, 15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 10-12 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFadden et al. in view of Miller et al. (J. Dairy Science 81 (Suppl. 1): p235 (1998)). McFadden et al. teach a method of inducing milk production in cows (line 2) comprising administering to cows a milk-secretion stimulation amount of estradiol and progesterone (line 5) and BST (bovine somatotropin) (line 3) (present claim 1). McFadden et al. fail to teach a method wherein the cow is subject to photoperiods.

Miller et al. teach a method of inducing milk production in cows comprising administering to cows BST and subjecting cows to milk-stimulating photoperiods (lines 1-2) (present claim 10, 12) wherein said photoperiods comprise approximately 12 hours of light and 12 hours of dark during each 24 hour period (ambient, line 7) (present claim 11). Miller et al. do not teach a method wherein estradiol and progesterone are administered in addition to the somatotropin and photoperiod exposure. Given the advantages of increasing milk yield in cows by administering BST and photoperiod exposure as taught by Miller et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to use McFadden's method of administering estradiol, progesterone and BST in addition to providing ambient, namely, approximately 12 hours of darkness and 12 hours of light, photoperiod exposure to yield

increased milk production. Thus, the inventions in claims 1, 10-12 and 22-24 were prima facie obvious to make and use at the time the claimed invention was made.

Claims 1, 10, 12, 13 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensinger et al. in view of Miller et al. Kensinger et al. teach a method of inducing milk production in fertile cows (lines 3 and 6-7) comprising administering BST (line 12), estradiol-17B (line 8) and progesterone (line 9) (present claim 1). Kensinger et al. do not teach subjecting the animals to milk-stimulating photoperiods.

Miller et al. teach a method of inducing milk production in cows comprising administering to cows BST and subjecting cows to milk-stimulating photoperiods (lines 1-2) (present claim 10, 12). Miller et al. do not teach a method wherein estradiol and progesterone are administered in addition to the somatotropin and photoperiod exposure. Given the advantages of increasing milk yield in cows by administering BST and photoperiod exposure as taught by Miller et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to use Kensinger et al.'s method of administering estradiol, progesterone and BST to fertile cows in addition to providing ambient, namely, approximately 12 hours of darkness and 12 hours of light, photoperiod exposure to yield increased milk production. Thus, the inventions in claims 1, 10, 12, 13 and 22-25 were prima facie obvious to make and use at the time the claimed invention was made.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFadden et al. in view of Kumar et al. McFadden et al. teach a method of inducing milk production in cows (line 2) comprising administering to non-pregnant cows a milk-secretion stimulation amount of estradiol and progesterone (line 5) via sponge and BST (bovine

somatotropin) via injection (line 3) (present claim 1) and 20 mg/kg of dexamethasone, a glucocorticoid, on or about day 10 (lines 6-9). McFadden et al. fail to teach a method wherein the amount of the estradiol is between .007 to .7 mg/kg, progesterone is between .0175 and 1.75 mg/kg, the BST is between 250-750 mg/kg and wherein the estradiol and progesterone are administed subcutaneously.

Kumar et al. teach a successful method of increasing milk production in cows by administering .1 mg/kg of estradiol and .1 mg/kg of progesterone subcutaneously (p. 665, col. 1, lines 11-21) and 500 mg of BST (p. 665, col. 1, lines 24-26). Kumar et al. do not teach the administration of a glucorticoid to increase milk production in cows. Given the advantages of administering glucocorticoid in addition to estradiol, progesterone and BST subcutaneously to increase milk production as taught by McFadden and the successful lower dosages of hormones to be administered as taught by Kumar et al., it would have been obvious to one of ordinary skill in the art at the time of the invention by applicant to administer subcutaneously low dosages of BST, progesterone, glucocorticoid and estradiol to increase milk production in non-pregnant cows.

Claims 1, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFadden et al. in view of Chakriyarat et al. (J. Dairy Sci 61: 1715-1724 (1978); cited in IDS, paper #4). McFadden et al. teach a method of inducing milk production in cows (line 2) comprising administering to cows a milk-secretion stimulation amount of estradiol, progesterone (line 5), BST (bovine somatotropin) (line 3) (present claim 1) and the glucocorticoid dexamethasone between days 10 and 17 (line 6). McFadden et al. fail to teach the administration of between .005 to .5 mg/kg of dexamethasone.

Chakriyarat et al. teach a method of inducing milk production in cows comprising administering estradiol, progesterone and .028 mg/kg of dexamethasone on day 18. Chakriyarat et al. fail to teach the administration of BST. Given the advantages of administering a combination of lactation-inducing hormones as taught by McFadden and the success of administering a small dosage of .028 mg/kg of dexamethasone as taught by Chakriyarat et al., it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to administer estradiol, progesterone, BST and a low dosage of about .028 mg/kg of dexamethasone to induce lactation in cows. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
June 29, 2003

Christopher S. Low